



BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-day Comment Request: Data and Specimen Hub (DASH) (Eunice Kennedy Shriver National Institute of Child Health and Human Development)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: Desk Officer for NIH.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Rohan Hazra, M.D., Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), National Institutes of Health, 6710B Rockledge Drive,

Room 2113, Bethesda, MD 20817, or call non-toll-free number (301)-435-6868 or E-mail your request, including your address to: rohan.hazra@nih.gov.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the Federal Register on April 27, 2018, page 18576 (Vol 83) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection Data and Specimen Hub (DASH) 0925-0774 exp. date 6/30/19–
REVISION Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH).

Need and Use of Information Collection:

This is a request to revise the previously approved submission to add the collection of additional information from Users who will request biospecimens, submit the Institutional Certification for data/biospecimen inventory, and submit DASH data/biospecimen Annual Progress Report for the NICHD Data and Specimen Hub

(DASH). DASH has been established by NICHD as a data sharing mechanism for biomedical research investigators. It serves as a centralized resource for investigators to store and access deidentified study data and biospecimen inventories—a list of biospecimens available at the NICHD Biorepository—from studies funded by NICHD. The potential for public benefit to be achieved through sharing study data and/or biospecimen inventories for secondary analysis is significant. NICHD DASH supports NICHD’s mission to ensure that every person is born healthy and wanted, that women suffer no harmful effects from reproductive processes, and that all children have the chance to achieve their full potential for healthy and productive lives, free from disease or disability, and to ensure the health, productivity, independence, and well-being of all people through optimal rehabilitation. Study data and biospecimen sharing and reuse will promote testing of new hypotheses from data already collected, facilitate transdisciplinary collaboration, accelerate scientific findings and enable NICHD to maximize the return on its investments in research.

Anyone can access NICHD DASH to browse and view descriptive information about the studies and study data archived in NICHD DASH without creating an account. Users who wish to submit or request research data and/or biospecimen inventories must register for an account.

Information will be collected from those wishing to create an account, sufficient to identify them as unique Users. Those submitting or requesting data and/or biospecimen inventories will be required to provide additional supporting information to ensure proper use and security of NICHD DASH study data and biospecimen inventories. The information collected is limited to the essential data required to ensure the management

of Users in NICHD DASH is efficient and the sharing of data and biospecimens among investigators is effective. The primary uses of the information collected from Users by NICHD will be to:

- Communicate with the Users with regards to their data submission, data requests and biospecimen requests
- Monitor data submissions, data requests and biospecimen requests
- Notify interested recipients of updates to data and biospecimen inventories stored in NICHD DASH
- Help NICHD understand the use of NICHD DASH study data and biospecimen inventories by the research community

All the data collected from use of NICHD DASH except for information provided in the annual progress reports are for the purposes of internal administrative management of NICHD DASH. Information gathered through the annual progress reports may be used in publications describing performance of the DASH system.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 204.

Estimated Annualized Burden Hours

Form	Number of Respondents	Number of Responses per Respondent	Average Time Per Response (in hours)	Total Annual Burden Hour
User Registration	200	1	5/60	17
Data Submission and Biospecimen Inventory Submissions	36	1	2	72

Data Request	60	1	1	60
Biospecimen Request	36	1	1	36
Data Use Annual Progress Report	60	1	10/60	10
Biospecimen Use Annual Progress Report	36	1	10/60	6
Institutional Certification Template	36	1	5/60	3
TOTAL	200	200		204

Dated: November 1, 2018.

Jennifer M. Guimond,

Project Clearance Liaison,

Eunice Kennedy Shriver National Institute of Child Health and Human Development,

National Institutes of Health.

[FR Doc. 2018-24313 Filed: 11/6/2018 8:45 am; Publication Date: 11/7/2018]